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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,473

Applicant(s)

VALE ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 9-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 7 is acknowledged.

Upon further consideration it was decided to rejoin Groups I and II because the claims of Group II are directed to the DNA encoding urocortin II protein of SEQ ID NO: 11, which is contained within SEQ ID NO: 10 of a urocortin II protein precursor peptide.

Claims 9-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 7.

Claims 1-8 are under examination in the instant office action.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

However, the provisional application 60/223,255 upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-8 of this application. Claims 1-8 are directed to mouse urocortin II proteins and the disclosed subject matter of the application 60/223,255 is directed to human sequences.

Applicant's claim for domestic priority under 35 U.S.C. 119(e) to the provisional application 60/273,969 is acknowledged and granted.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It was not executed in accordance with either 37 CFR 1.66 or 1.68. The signature of the inventor Wylie is not present.

Specification

4. The specification of the instant application, including the claims, is not in compliance with the requirements for Sequence Identifiers (see MPEP 2422.03). The proper form of presenting a sequence identifier is "SEQ ID NO:", followed by a number of a sequence. Appropriate correction is required.

Claim Objections

5. Claim 3 is objected to because of the following informalities: in recitation "wherein said protein has a amino acid sequence", perhaps should be "wherein said protein has an amino acid sequence". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is directed to a DNA encoding urocortin II and DNA, which hybridizes to the complement of the DNA encoding urocortin II, and to the DNA, which is degenerative of the genetic code and which encodes urocortin II protein. Claims 2-8 depend from claim 1. However, the instant specification fails to describe the entire genus of proteins, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecules which encode proteins which have the amino acid sequence of SEQ ID NOS:10 or 11. The subject matter, which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are nucleic acid molecules encoding urocortin II and nucleic acid molecules, which hybridize to the complement of the DNA encoding urocortin II, and to the DNA, which is degenerative of the genetic code and which encodes urocortin II protein. First, the claims are not limited to nucleic acid molecules encoding proteins with a specific amino acid sequence. The claims only require the DNA to share some degree of structural similarity to the DNA that encodes proteins of SEQ ID

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NOS:10 and 11. The specification only describes the DNA, which encodes proteins having the amino acid sequence of SEQ ID NOS:10 and 11 and fails to teach or describe any other DNA, which lacks the nucleic acid sequence and yet encodes proteins with the activities possessed urocortin II or urocortin II precursor proteins. Therefore, the claims are unduly broad and there is a lack of guidance or teaching regarding structure and function because there are only two examples provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the nucleic acid molecules, which encode proteins of SEQ ID NOS: 10 and 11. The specification does not provide a complete structure of those DNA encoding urocortin II and DNA, which hybridizes to the compliment of the DNA encoding urocortin II as well as the structure of the DNA, which is degenerative of the genetic code and which encodes urocortin II protein. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those DNA encoding urocortin II and DNA, which hybridizes to the compliment of the DNA encoding

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urocortin II, and the DNA, which is degenerative of the genetic code and which encodes urocortin II protein) because the specification teaches only the embodiments of DNA, which encodes SEQ ID NOS:10 and 11. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. Claims 4-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

Claims 4-8 encompass “[A] vector capable of expressing the DNA” (see claim 4) or “vector expressing urocortin II protein” (see claim 6), whereas a vector can “comprise” a DNA and “encode” a protein. It is a host cell comprising that vector, which “expresses” any protein encoded thereby. Therefore, it would require undue experimentation for a skilled artisan to discover how to make a “vector capable of expressing the DNA” because the instant specification fails to provide any guidance to support the recited limitation and there is no information disclosed in the prior art on the claimed subject. Moreover, there is no indication in the art that a vector is capable of expressing a protein; therefore, one skilled in the art would not recognize how to make the claimed invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 is vague and indefinite in so far as it employs the term “urocortin II” as a limitation. This term appears to be novel, and without a reference to a precise amino acid sequence identified by a proper SEQ ID NO: one cannot determine the metes and bounds of “DNA encoding urocortin II”. Moreover, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a “urocortin II”, an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

Claim 1 is further indefinite for recitation of “DNA different from isolated DNAs of (a) and (b) above in codon sequence due to the degeneracy of the genetic code”. The limitation of “degeneracy” is only relevant in reference to a specific nucleotide sequence encoding a particular protein. In the instant case, since parts (a) and (b) are not limited to DNAs encoding specific proteins, the limitation of “DNA different from isolated DNAs of (a) and (b) above in codon sequence due to the degeneracy of the genetic code” is vague and ambiguous.

Finally, claim 1 is vague for recitation “antisense compliment”. The recitation seems to be redundant and confusing. Clarification is required.

10. Claim 7 is indefinite and confusing because there is not antecedent basis for the plural form of “a cell” in the Markush group recited therein. Recitation of “said cell is selected from

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group consisting of a bacterial cell, a mammalian cell, a plant cell and an insect cell” would obviate this ground of rejection.

11. Claims 2-6 and 8 are indefinite for being dependent from the indefinite claims.

Conclusion

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant’s representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

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Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
September 3, 2002

OC


JOHN ULM
PRIMARY EXAMINER
GROUP 1800